K093109

807.87(h) 510(k) Summary

JUN 18 2010

As required by Section 807.92 (a)

(1) DATE OF PREPARATION: 2010-6-9

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. NovoTwist® needle meets all applicable product and quality standards for hypodermic single lumen needle products.

SUBMITTER'S NAME AND ADDRESS:

Novo Nordisk Inc.
100 College Road West
Princeton, New Jersey 08540

Contact Person:
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(2) NAME OF DEVICE:

Proprietary Name:	NovoTwist® *needle* 30G x 8 mm 32G Tip x 5mm
Common or usual name:	Sterile disposable hypodermic needle
Classification:	Hypodermic single lumen needle (21 CFR 880.5570)
Class:	Class II

(3) SUBSTANTIAL EQUIVALENCE:

NovoTwist® 30G and 32G Tip needles are disposable needles which are substantially equivalent to the Novo Nordisk's NovoFine® 32G Tip (0.23/ 0.25 mm) x 6 mm disposable needle, cleared under 510(k) K062500 and K090111, to the NovoFine® Autocover® 30G x 8 mm disposable needle, cleared under 510(k) K050106, and to the BD Pen needle, cleared under 510(k) K051899.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and supplied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statement related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US patent laws or their applications by the court.

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(4) DEVICE DESCRIPTION:

NovoTwist® needle is designed for single use in conjunction with Novo Nordisk injection delivery devices built with bayonet coupling. Prior to giving an injection, the protective tab is removed from the outer needle cap of the single-use disposable needle. With the disposable needle remaining in the outer needle cap, it is then pressed onto the injection delivery device with a bayonet coupling and twisted a quarter of a revolution until tightness and a confirmatory click is heard. Then the outer and inner caps of the needle are removed. Injection is performed by following the procedure described in the User Manual provided with the pen injection device and instructions from your health care professional.

After the injection, the needle is removed from the skin. The needle is detached from the injection device and disposed of in accordance with national/local regulations. For each subsequent injection, another disposable needle must be used. Function checks for the delivery device can be performed with the NovoTwist® needles by using the needle cap.

The NovoTwist® needle is used in exactly the same manner as the NovoFine® and the BD Pen needle except it is built with an improved attachment mechanism. NovoTwist® needle is attached to the delivery device via a bayonet thread. This allows the user to press down and twist the needle a quarter of a revolution instead of tightening through several revolutions as with the NovoFine® needle, BD pen needle, and many other commercially marketed hypodermic needles that operate on the same principles. This improved mechanism is intended to reduce the attachment time. In addition, users can hear a confirmatory click when the NovoTwist® needle is attached correctly to the device. This user friendly feature is designed to ensure the needle is attached to the device correctly before beginning the injection.

(5) INTENDED USE:

NovoTwist® needles are intended for use with pen injector devices for the subcutaneous injection of insulin, liraglutide and somatropin.

(6) TECHNOLOGICAL CHARACTERISTICS:

The NovoTwist® needle is considered substantially equivalent to the NovoFine® 32G Tip needles, the NovoFine® Autocover® 30G needles, and the BD pen needles in intended use, technology, principle of operation, materials and performance. For a detailed side by side comparison to

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Novo Nordisk's NovoFine® needles and the BD needles cleared by the Agency, please see Table 1: Comparison to a legally marketed device. N/A is used where the documentation is considered to be proprietary information of BD.

Materials in NovoTwist® 30G are identical to those in the NovoTwist® 32G Tip needles. NovoTwist® needles consist of almost the same components and materials as NovoFine® Autocover® 30G and NovoFine® 32G Tip needles. A detailed side by side comparison of the materials in NovoTwist® 30G and 32G Tip needles with those in the NovoFine® needles is presented in Table 2: Material description of NovoTwist®.

In conclusion, the difference between the NovoTwist® and the NovoFine® and BD Pen needles is the attachment mechanism, and it does not raise any significant issues of safety and effectiveness.

Table 1 Comparison to a legally marketed device:

Parameters	NovoTwist® 32G Tip	NovoTwist® 30G	NovoFine® 32G Tip	NovoFine® Autocover® 30G K050106	BD Pen Needle 29G, 30G, 31G K051899
Marketing Status	TBD	TBD	K062500, K090111		
Intended use	Subcutaneous injection of insulin, liraglutide and somatropin	Subcutaneous injection of insulin, liraglutide and somatropin	Subcutaneous injection of insulin, liraglutide and somatropin	Subcutaneous injection of insulin	Subcutaneous injection of drugs, including insulin and exenatide
Product type	Hypodermic pen needle	Hypodermic pen needle	Hypodermic pen needle	Hypodermic pen needle	Hypodermic pen needle
Materials	See Table 2	See Table 2	See Table 2	See Table 2	N/A
Durability	2 years from production date	2 years from production date	5 years from production date	3 years from production date	N/A
Biocompatibility	DS/EN ISO 10993-1, see Appendix E	DS/EN ISO 10993-1, see Appendix E	DS/EN ISO 10993-1, see Appendix E	DS/EN ISO 10993-1, Appendix E	N/A
Reuse	N/A – single use	N/A – single use	N/A – single use	N/A – single use	N/A – single use
Labeling	See Section 5	See Section 5	See Section 5	See Section 5	N/A
Specifications					
Outer Diameter, Tip	0.22-0.25 mm	N/A	0.22-0.25 mm	N/A	N/A
Outer Diameter; cylindrical part	0.25-0.27 mm	0.30-0.32 mm	0.25-0.27 mm	0.30-0.32 mm	N/A
Inner Diameter	0.145-0.16 mm	0.165-0.185 mm	0.145-0.16 mm	0.165-0.185mm	N/A
Wall Thickness, Tip	0.03-0.053 mm	N/A	0.03-0.053 mm	N/A	N/A
Wall Thickness, Cylindrical part	0.045-0.063 mm	0.058-0.078 mm	0.045-0.063 mm	0.058-0.078 mm	N/A
Total Length	14.82-15.88 mm	17.85-18.85 mm	15.82-16.88 mm	33.87-34.93 mm	N/A
Length from Hub	5 mm	8 mm	6 mm	8 mm	5, 8, 12.7 mm
Gauge	31/32 Tip	30	31/32 Tip	30	31, 30, 29
Tip Configuration	1.st and 2.nd grinding and glass blasting	1.st and 2.nd grinding and glass blasting	1.st and 2.nd grinding and glass blasting	1.st and 2.nd grinding and glass blasting	N/A
Cover Color	Light Blue (RAL 5012)	Yellow (RAL 1021)	Light Blue (RAL 5012)	Yellow (Pantone 116U)	N/A
Cover Strength	Pmin = 56mBar	Pmin = 56mBar	Pmin = 70mBar	Pmin = 70mBar	N/A
Hub/≤needle≥bond strength	Fmin = 22 N	Fmin = 22 N	Fmin = 22 N	Fmin = 22 N	N/A
Needle Stick Prevention Features					
Activation Process	N/A	N/A	N/A	Passive/Automatic	N/A
Safety Indicator	N/A	N/A	N/A	Visual	N/A
Safety Override	N/A	N/A	N/A	No	N/A

Table 2 Material description of NovoTwist® needles:

Component	NovoTwist® 30G and 32G Tip [1] Manufacturing site NMS	NovoFine® Autocover® 30G [2] Manufacturing site NMS	NovoFine® 32G Tip Manufacturing site Nipro, Japan
1. The hub	Polypropylene (PP) Color: White	Polypropylene (PP) Color: Moplen HP548R Or Moplen HP548R White Or RF365MO Neutral	Polypropylene (PP)
2. Glue	Eccobond, 927-10-EF One component epoxy adhesive Color: Light yellow	Eccobond, 927-10-EF One component epoxy adhesive Color: Light yellow	Eccobond 927-10-E One component epoxy adhesive Color: Light yellow
3. The inner cap	Polyethylene (PE) Color: Transparent	N/A	Polyethylene (PE)
4. The outer cap	Polypropylene (PP) Color: Transparent Blue	Polypropylene (PP) Color: Moplen HP548R Or Moplen HP548R White Or RF365MO Neutral	Polypropylene (PP)
5. The cannula	Stainless steel AISI 304/JISG 4305 DIN-kurzname: X 5 CrNi 18 9	Stainless steel AISI 304/JISG 4305 DIN-kurzname: X5 CrNi 18 9	Stainless steel AISI 304/JISG 4305 DIN-kurzname: X 5 CrNi 18 9
Ad 5. Lubricating oil for the patient needle	MDX4-4159 Medical Grade Dispersion (partly hardened silicone)	MDX4-4159 Medical Grade Dispersion (partly hardened silicone)	MDX4-4159 Medical Grade Dispersion (partly hardened silicone)
Ad 5. Lubricating oil for the back needle	Medical Fluid Silicone Oil 12500 cSt	Medical Fluid Silicone Oil 12500 cSt	Medical Fluid Silicone Oil 12500 cSt
6. The sealing paper/ protective tab	Gas permeable sealing paper 60 g/m² for steam sterilization	Gas permeable sealing paper 60 g/m² for steam sterilisation	Bactite 60K 43 g/m² coated with PS-118 lacquer 6 g/m² for ethylene oxide sterilization

Note 1: See Figure 3 regarding the drawing of individual components.

Note 2: Some of the specific components and materials used for NovoFine® Autocover® 30G is not shown in the table as they are related to the unique shield mechanism of prevention of needle stick injuries.

807.87(h) 510(k) Summary (continued)

As required by Section 807.92(b)

(1) NON-CLINICAL TESTS:

NovoTwist® 30G and 32G Tip needles have been subjected to many non-clinical tests throughout the development by Novo Nordisk R&D, and these tests comply with ISO 11608-2:2000 Pen-injectors for medical use - Part 2: Needles - Requirements and test methods.

First, several prototype tests with NovoTwist® needles were conducted to evaluate the performance and functionality of the needles.

Second, NovoTwist® needles are subjected to a final design verification test. The needle samples tested are manufactured, sterilized, packaged and labelled on validated equipment and QA-released in accordance with cGMP for Medical Devices (ISO 13485:2003 Medical devices - Quality management systems Requirements for regulatory purposes). The final design verification test consists of 34 mechanical and visual tests (Appendix D of original 510(k) submission). Some of the key design verification tests performed include the bubble leak test to ensure sterility in accordance with ISO 11607-1:2006 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems; Freedom from defects in accordance with ISO 7864:1993 Sterile hypodermic needles for single use, i. e. defect needle point, patient needle point, silicone on patient-end needle, bond between hub and needle tube and visual control of quality of sealing. In summary, the final design verification test supports that NovoTwist® needles meet the specified requirements and that the needles can be safely used in various real-life situations of handling and use according to Instructions for Use.

Third, shelf life test has been performed on final released NovoTwist® 30G and 32G Tip needles in accordance with ISO 11607-1:2006 (see Appendix 3 in the submission of June 10, 2010).

Fourth, the cannula and silicone oil are the only components of the needle in contact with human tissue, and the composition of the cannula and silicone oil of NovoTwist® needles are identical to that of NovoFine® needles, the substantially equivalent device (see Table 2). Therefore we reference the biocompatibility tests to those previously conducted for the NovoFine® needles in accordance with ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system, which have been cleared by the Agency (see Appendix E in the original 510(k) submission).

Finally, handling test and usability test are performed (see Appendix G in the original submission).

The NovoTwist® needles are manufactured in accordance with current Good Manufacturing Practices for Medical Devices.

(2) CLINICAL TESTS:

No clinical tests are required.

(3) CONCLUSIONS DRAWN FROM THE NON-CLINICAL AND CLINICAL TESTS:

Based on the design equivalency and the functional testing, Novo Nordisk had determined that the NovoTwist® needle is substantially equivalent to the NovoFine® 32G Tip needle (K062500, K090111), the NovoFine® Autocover® 30G needle (K050106), and the BD pen needle (K051899) which are currently marketed in the United States. Differences between the devices do not raise any significant issues of safety and effectiveness.

Mary Ann McElligott, Ph.D.
Associate Vice President, Regulatory Affairs
Novo Nordisk Inc.

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 18 2010

Cindy Cao, Ph.D.
Senior Manager, Regulatory Affairs
Novo Nordisk Incorporated
100 College Road West
Princeton, New Jersey 08540-7810

Re: K093109
Trade/Device Name: NovoTwist® Needle, Models 30G x 8mm (1/3") & 32G Tip x 5mm (1/5")
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: June 10, 2010
Received: June 11, 2010

Dear Dr. Cao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K093109

Device Name: NovoTwist® *needle*

32G Tip x 5mm Disposable Needle

30G x 8mm Disposable Needle

Indications For Use: NovoTwist® needles are intended for use with pen injector devices for the subcutaneous injection of insulin, liraglutide and somatropin

Prescription Use _____ AND/OR Over-The-Counter Use ____X_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093109